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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,428	08/14/2006	Patrice Richard	Q94528	4756

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EXAMINER	
EISEMAN, ADAM JARED	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
04/15/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/577,428	RICHARD ET AL.	
	Examiner	Art Unit	
	ADAM J. EISEMAN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-23,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-12,14-23,25 and 26* is/are rejected.

7)☒ Claim(s) *13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/19/2009 has been entered.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-4, 6, 11, 15-17, 23 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton (US 7,179,232) in view of Twersky (US 4,445,788) and Davis et al (US 5,571,097).

Sutton discloses a bone marrow extraction device comprising:

- A grip zone (element 52)
- A needle (element 24) presenting at least one side orifice (element 26)
- The device characterized in that the needle is connected to a needle holder (enlarged proximal portion of inner needle; figure 3), and in that a protective sleeve (outer cannula, element 16) surrounds at least a part of said needle (see figure 1-3), said protective sleeve being mounted to

move relative to said needle between a closed position the side orifice and an open position of the side orifice (column 5, lines 16-28)

- A mating arrangement between the needle holder and the base of the sheath to connect the inner and outer cannula and permit rotational movement of the cannula so as to selectively align the orifices of the cannula between the open and closed position (column 4, line 56 to column 5, line 9)

However, Sutton does not disclose fastener means on the protective sleeve to engage reception means on the needle holder so as to hold the protective sleeve in the open or closed position; or that the fastener means include a pair of claws diametrically opposite to one another, each claw being pivotally mounted and presenting a manual actuation surface and projection.

Twersky teaches the use of a detent mechanism (element 29) used to lock a sheath into either an open position where apertures in the sheath aligned with inner apertures or to a closed position where the sheath shields the apertures (column 3, lines 9-21).

Davis teaches fastener means for connecting a sheath and an inner needle comprising diametrically opposite claws (element 76) each claw being pivotally mounted (about connection point on cap) and presenting manual actuation surface (element 80) and a projection (element 84) (see figures 9 and 10).

Regarding claims 1-4, 6, 11, 15-17, 23 and 25-26; Sutton teaches the use of indicia (elements 58) on the sheath handle and needle holder which place the apertures

in an open position when aligned and a closed position when misaligned (column 6, lines 48-62). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Sutton to use a locking/fastening mechanism as taught by Twersky for holding the sheath and needle apertures in an open or closed position in order to provide the user with the ability to quickly and assuredly move the orifice between the open and closed positions (as suggested by Sutton's alignment indicia which indicate open and closed positions).

Further regarding claims 1-4, 6, 11, 15-17, 23 and 25-26; it would have been obvious to one of ordinary skill in the arts at the time of the invention to substitute the fastening/locking means of the Sutton/Twersky combination with Davis' diametrically opposed claw fastening means in order to provide an actuation surface for easier connection and locking.

Further regarding claim 2; Sutton discloses that the outer cannula is mounted to turn about the inner cannula.

Further regarding claim 3; Sutton discloses that the sheath includes at least one side opening (element 20) that is positioned facing the orifice of the needle in the open position (column 5, lines 16-28).

Further regarding claim 4; Sutton discloses that the handle part of the sheath (element 32) is used for mating the sheath to the needle.

Further regarding claim 6; Davis teaches a receiving groove/ledge for receiving the projections of the claws in order for the fastening means to hold (see figures 9 and 10).

Further regarding claim 11 and 15-16; Sutton discloses that the device can be used to extract bone marrow.

Further regarding claims 15-17; Sutton discloses an outlet port (element 54) connected to the needle for connection to any well known medical device for providing suction (column 6, lines 40-47). Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a vacuum pump as the suction means as they are a well known device for providing suction and that pedals are well known actuators for actuating medical devices.

Further regarding claim 23; it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the device in sterile packaging as it is well known in the art of medical devices to use sterile packaging to prevent infection and disease.

Further regarding claim 25; Davis's fastener means prevent radial force from being applied to the protective sheath (see figures 9 and 10).

4. Claims 7-10, 12, and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton in view of Twersky and Davis as applied to claim 1 and 11 above, and further in view of Shapira (US 6,110,176).

The Sutton/Twersky/Davis combination is described in the rejection of claims 1 and 11 above; however it does not disclose a mixing chamber with an inlet and outlet port; providing an anticoagulant to the inlet channel; or connecting the outlet channel to a bone marrow collection vessel.

Shapira teaches a system and method for extracting bone marrow comprising: extracting bone marrow using the bone marrow extraction needle (element 85); mixing the extracted bone marrow with an anticoagulant solution; and transferring the mixed bone marrow solution to a collection chamber (column 8, lines 40-59). Furthermore, Shapira teaches that the solution can be mixed with the bone marrow before being transferred to the collecting means (column 8, lines 54-59).

Regarding claims 7-10, 12, and 14-19; Shapira teaches the method of extracting bone marrow, mixing a solution with bone marrow, and transferring the mixed solution to a collection chamber but does not disclose the specifics of the apparatus used to perform extraction/mixing operation. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the Sutton/Twersky/Davis combination as the bone marrow extraction needle used in Shapira'a method as simple substitution of one known element with another.

Further regarding claim 7-10, 12 and 14-19; Shapira discloses a mixing chamber in the bone marrow extraction unit (see figure 4; mixing chamber being the area where the infusion fluid from the inlet port, the bone marrow, and outlet port meet in the hollow area of the extraction device). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Sutton/Twersky combination to include a mixing chamber where mixing of the infusion fluid and bone marrow occurs having an inlet port for the infused solution and an outlet port for transferring the mixed bone marrow/infusion solution to the collection chamber as taught by Shapira (figure 4; column 8, lines 40-59). Furthermore, it would have been obvious to one of ordinary skill

in the art to include this mixing chamber anywhere in the extraction device as taught by Shapira where the space is in fluid communication with the biopsy site, inlet port and outlet port but before the collection chamber, including in the needle holder, in the handle, or as an insert to the Sutton/Twersky bone marrow extraction needle. It would have been obvious to try as choosing from a finite number of predictable solutions with reasonable expectation of success.

Further regarding claim 14; Shapira disclose extracting the mixed bone marrow to a collection chamber. It would have been obvious to one of ordinary skill in the art that a Sutton/Twersky/Shapira combination would have an outlet channel to extract the mixed bone marrow to the collection chamber.

Further regarding claim 15-17 and 19; Shapira discloses use of suction means to extract the bone marrow from the extraction site to the collection chamber. It would have been obvious to one of ordinary skill in the art a the time of the invention to use any well known suction means for providing suction to the needle including vacuum pumps, pedal actuated pumps, and timed pumps.

Further regarding claim 18; Shapiro discloses a mixing chamber having an inlet and outlet channel. It would have been obvious to one of ordinary skill in the art at the time of the invention to use any well known configuration of inlet and outlet channels for a mixing chamber to create effecting mixing including modifying the inlet valve to project the infused fluid into the mixing chamber towards the outlet channel to create a Venturi effect and effectively promote mixing.

5. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton in view of Twersky and Davis as applied to claim 1 above, and further in view of Morawski (US 2004/0010236).

The Sutton/Twersky/Davis combination is described in the rejection of claim 1 above; however it only discloses the use of the device for the extraction of bone marrow.

Morawski teaches that although a device is described as a bone marrow aspiration device, one of ordinary skill could use an aspiration needle to inject a fluid (abstract).

Regarding claims 20-22; it would have been obvious to one of ordinary skill in the art at the time of the invention to use the Sutton/Twersky/Davis combination to inject bone marrow into a patient as taught by Morawski.

Further regarding claim 21-22; Sutton discloses that the needle can be connected to a medical syringe or similar medical device. It would have been obvious to one of ordinary skill in the art at the time of the invention that the syringe could be filled with bone marrow, thus acting as a bone marrow reservoir, and that the syringe could be electrically driven as automatic syringe drivers are well known in the art.

Allowable Subject Matter

6. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record teaches a mixing chamber wherein part of the mixing takes place within the bone by direct infusion using a irrigation fluid such as saline. The current invention and claimed in claim 13 requires an anticoagulant to be input through the inlet port to the mixing chamber. The prior art of record relied on for the rejection of claims 7-10, 12, and 14-19 could not be used with an anticoagulant as described in claim 13 because it is not safe to directly infuse an anticoagulant into the bone of the body, and thus is indicated as allowable over the prior art of record as the mixing chamber would be required to be exterior the bone so that no anticoagulant could enter the body.

Response to Amendment

The applicant's amendments and arguments/remarks have been fully considered but are moot in view of the new grounds of rejection presented above.

Specifically the applicant amended claims 1 and 26 to recite the combination of claims 5 and 24 in order to overcome the previously held rejections. Accordingly the examiner provided the new Davis reference in order to meet the limitations of the claims. The Davis reference teaches the use of diametrically opposed claws being pivotally mounted and presenting a manual actuation surface and projection for engaging and disengaging the claws (see figures 9-10). Further more, it would have been obvious to one of ordinary skill in the art at the time of the invention that the location of Davis' fastening means could be located on the sheath and the

corresponding grooves for receiving the projections could be located on the inserted needle as obvious to try.

Furthermore, the applicant's argument regarding the mixing chamber in claims 7-10, 12 and 14-19 is non persuasive. As previously pointed out in the advisory action the applicant argues that Shapira does not teach a mixing chamber in the device because the irrigation fluid is delivered into the bone. The examiner disagrees with the applicant's argument. Shapira claims that the irrigation fluid is passed to the "extraction site". The examiner interprets the extraciton site as the location where the device and bone meet. If one were to look at figure 4, the extraction site would be where the device is in contact with the bone. At this site there is a large cavity at the end of the device where the mixed fluid and bone marrow is extracted via passage element 53. Furthermore the device dicloses this space has ridges, elements 62, which further mixes the bone marrow and irrigation fluid. Thus by further mixing the irrigation fluid and bone marrow in this space, it may be inherently described as a mixing chamber.

However, the examiner finds the applicant's argument in regard to claim 13 to be persuasive. As citing in the allowable subject matter section above; the examiner concedes that as pointed out by the applicant the irrigation fluid of Shapira could not be replaced by anticoagulant because it would not be safe to inject anticoagulants into the bone.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM J. EISEMAN whose telephone number is (571)270-3818. The examiner can normally be reached on Monday-Friday 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AE
4/10/2010
/A. J. E./
Examiner, Art Unit 3736

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